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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,210	07/09/2004	Margaret Forney Prescott	TX/4-32304A	3236

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,210	PRESCOTT ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-13* is/are pending in the application.

4a) Of the above claim(s) *4-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-22-04; 11-7-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1 and 4-13 are presented for examination.

Applicants' preliminary amendment filed July 9, 2004; and information disclosure statements filed October 24, 2004 and November 7, 2007 have been received and entered.

Applicants' election filed January 17, 2008 in response to the restriction requirement of July 18, 2007 has been received and entered. The applicants elected the invention described in claim 1 (Group I) without traverse.

Claims 4-13 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating restenosis in diabetic patient or reducing vascular access dysfunction in a subject with rapamycin or a derivative thereof having mTOR properties, does not reasonably provide enablement for preventing restenosis in a diabetic patient or preventing vascular access dysfunction in a subject with rapamycin or a derivative thereof. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

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The claimed invention relates to a pharmaceutical composition for preventing restenosis in a diabetic patient or preventing vascular access dysfunction in a subject with rapamycin or a derivative thereof.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventive therapies for restenosis in diabetic patients or vascular access dysfunction in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any "causes" of restenosis and vascular access dysfunction.

The amount of direction or guidance provided and the presence or absence of working examples

There are no examples showing the instant compound, rapamycin or a derivative thereof, in fact, prevent restenosis or vascular access dysfunction in a subject not presently at risk of or predisposed to developing such a disease or disorder. No examples showing the instant compound, rapamycin or a derivative thereof is administered to a healthy subject not having restenosis or vascular access dysfunction, and the administration of the instant compound will prevent the subject from becoming afflicted with restenosis or vascular access dysfunction during its lifetime. Current modes of treatment are known, but there are no known agents,

which can be, prevent the causes of restenosis or vascular access dysfunction in a healthy subject.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which cause would be prevented for restenosis or vascular access dysfunction. The skilled artisan would expect the interaction of a particular drug in the prevention of causes of restenosis or vascular access dysfunction to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification sets forth neither such understanding nor any criteria for extrapolating beyond the administration of the compound to inhibit restenosis or vascular access dysfunction. Even for the data presented, no direction is provided to prevent specific causes of restenosis or vascular access dysfunction. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many conditions that may lead to restenosis or vascular access dysfunction to discover which cause is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claim 1 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "mTOR properties". What does this phrase mean? Applicants may wish to spell out the name of this phrase so that one who is not skilled in the art can understand the phrase language.

Claim 1 is not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sehgal et al. (3,929,992) or Cottens et al. (WO 94/09010).

Sehgal et al. teach rapamycin and it can be used in combination with pharmaceutical acceptable carriers (see column 4, lines 18-21).

Note that a composition comprising the same ingredients as the claimed composition will inherently possess the qualities recited herein. Note further that recitation of intended use does not further limit a claim drawn to a composition.

Cottens et al. teach rapamycin derivatives and the derivatives can be combined together with a pharmaceutically acceptable diluent or carrier (see page 39, claim 7).

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Note that a composition comprising the same ingredients as the claimed composition will inherently possess the qualities recited herein. Note further that recitation of intended use does not further limit a claim drawn to a composition.

Claim 1 is not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin E. Weddington
Primary Examiner
Art Unit 1614

Art Unit: 1614

/Kevin E. Weddington/
Primary Examiner, Art Unit 1614